IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	Confirmation No.: 4939
Gary K. Michelson	)	
Serial No.: 10/674,971	)	Group Art Unit: 3738
Filed: September 30, 2003	)	Examiner: David H. Willse
For: METHOD FOR INSERTING AN INTERBODY SPINAL FUSION IMPLANT HAVING AN ANATOMICALLY CONFORMED TRAILING END	)	

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Commissioner for Patents
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Sir:

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Further to the Final Office Action of February 16, 2011 ("Final Action"), Appellant submits the following remarks for consideration by the Members of the Pre-Appeal Conference:

I. Brief Background

Independent claims 29 and 39 are generally drawn to a method of inserting an artificial implant into a disc space between two adjacent vertebral bodies (see, e.g., Fig. 6C). Appellant filed an Amendment After Final on May 16, 2011 ("Amendment"), amending independent claim 29, and traversing the finality of the Final Action and the Examiner's rejections of all claims under 35 U.S.C. §§ 102(b) and 103(a). In the Advisory Action of June 1, 2011 ("Advisory Action"), the Examiner disagreed that the finality of the Final Action was improper, entered the claim amendment, but did not address Appellant's arguments traversing the rejections over prior art.

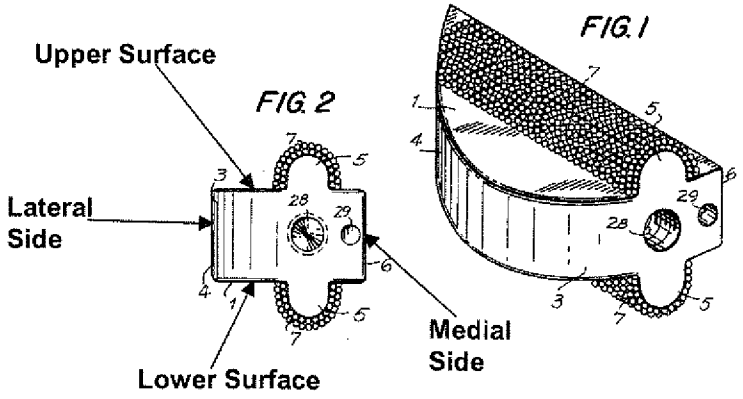
II. Clear Errors or Omissions

The Examiner rejected claims 29, 30, 33-36, 39-41, 44-47, 50-59, 62, 63, and 65-67 under 35 U.S.C. § 102(b) over U.S. Patent No. 4,714,469 to Kenna ("Kenna"); rejected claims 31, 32, 42, 43, 64, and 68 under 35 U.S.C. § 103(a) over Kenna in view of U.S. Patent No. 5,192,327 to Brantigan ("Brantigan"); and rejected claims 37, 38, 48, and 49 under 35 U.S.C. § 103(a) as being unpatentble over Kenna in view of Publication No. WO 98/48738 to Crozet (via related U.S. Patent No. 6,855,168) ("Crozet"). Each error is addressed below.

(1) The rejection of independent claim 29 is erroneous at least because Kenna does not disclose each and every recitation of independent claim 29.

(a) Kenna does not disclose arcuate upper and lower surfaces "from the lateral side to the medial side along the maximum width."

Independent claim 29 recites that "the upper and lower surfaces being arcuate from the lateral side to the medial side along the maximum width of said implant and in a plane transverse to a mid-longitudinal axis of the implant." Kenna discloses an implant having "a first surface 1 and a second surface 2" (e.g., upper and lower surfaces, respectively); "curved portion 4" (e.g., lateral side); "straight side 6" (e.g., medial side); and arcuate "protuberances 5." (See Kenna, col. 3, lines 34-35; 39, 55; Figs. 2 and 3.) Figs. 2 and 4 of Kenna show that upper and lower surfaces 1, 2 face up and down, respectively, while sides 4 and 6 face left and right, respectively. The Examiner contends that "lateral and medial sides as claimed may alternatively be viewed as including the upper and lower flat surface portions of the Kenna implant." (Final Action, p. 2, lines 20-21.) The MPEP sets forth that the Examiner must use the "broadest reasonable interpretation." (MPEP § 2111, p. 2100-37, col. 2 (Rev. 7, Sept. 2008) (emphasis added).)



Surfaces 1, 2, 4, and 6 are separate surfaces as described by Kenna. Surfaces 4, 6, are "sides," while surfaces 1, 2, are *prima facie* upper and lower surfaces because they are oriented at 90° to sides 4, 6 (see Figs. 1 and 2 above). Appellant respectfully submits that it is unreasonable to construe upper and lower facing surfaces that are oriented 90° to the sides as something other than an upper or lower surface, particularly when the claims treat these surfaces as separate elements, and the Kenna disclosure treats them as separate surfaces. Moreover, the Examiner's own language indicates that surfaces 1, 2 are better characterized as upper and lower surfaces rather than side surfaces. (See Final Action, p. 2, line 21; and p. 3, line 1.)

Fig. 2 of Kenna shows that arcuate protuberance 5 of upper and lower surfaces 1, 2 does not extend from curved side 4 to straight side 6. Accordingly, neither upper surface 1 nor lower surface 2 is arcuate "from the lateral side to the medial side along the maximum width of said implant and in a plane transverse to a mid-longitudinal axis of the implant" as recited in independent claim 29.

(b) Kenna does not disclose "positioning the leading end."

Independent claim 29 further recites "positioning the leading end of the implant so that at least a portion of the implant proximate the leading end between the medial side and the mid-longitudinal axis overlies the apophyseal rim without substantially protruding from the spine." Kenna teaches that "[w]hen the grooves are drilled each drill bit is removed and replaced by a spacer to maintain the spaces between the vertebrae." (Kenna, col. 5, lines 66-68.) Kenna does not disclose or show that the leading ends of the implants are positioned such that portions of the implants proximate the leading end between the medial side and the mid-longitudinal axis overlie the apophyseal rim.

(2) The rejection of independent claim 39 is erroneous at least because Kenna does not disclose each and every recitation of independent claim 39.

(a) Kenna does not disclose that each of the lateral and medial sides is "at least in part straight."

Independent claim 39 recites that "each of the lateral and medial sides" of the first and second implants is "at least in part straight in a direction from the leading end to the trailing end along at least a portion of the length" of the implant. The Examiner contends that "said upper and lower flat surface portions are straight along the implant length." (Final Action, p. 3, lines 1-2.) Claim 39 does not require the upper and lower surfaces to have the straight portion, but both of the medial and lateral sides to have the straight portion. Kenna fails to disclose this feature. Fig. 3 of Kenna shows that side 4 of the implant is curved and side 6 of the implant is straight.

(b) Kenna does not disclose "positioning the leading end."

Independent claim 39 further recites "positioning the leading end of each implant so that at least a portion of the implant proximate the leading end between the medial side and the mid-longitudinal axis overlies the apophyseal rim without substantially protruding from the spine," which is not disclosed or shown in Kenna.

(3) The respective rejections of dependent claims 31, 42, 64, and 68 are clearly erroneous. Claims 31 and 42 each recite that the "implant is a fusion implant having a hollow therein, further

comprising loading the implant with a fusion promoting material prior to inserting the implant." Claims 64 and 68 each recite "providing the implant with each of the upper and lower surfaces including at least one opening adapted to communicate with one of the adjacent vertebral bodies, the openings in the upper and lower surfaces being in communication with one another."

The Examiner admits that "Kenna lacks openings communicating with a hollow space," and contends that "[t]o so modify Kenna [in view of Brantigan] would have been obvious in order to enhance the long-term stability." (See Final Action, p. 3, lines 4-8.) Appellant submits that the Examiner's rationale for making the combination falls short of the standard articulated in *KSR* because Kenna already accomplishes without modification what the Examiner states is the reason to combine the teachings of Kenna and Brantigan. (See, e.g., MPEP § 2141 (III), p. 2100-119, cols. 1-2 (Rev. 6, 2007) ("[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness").) Kenna teaches that "placement of the implant between adjacent vertebrae tissue/bone ingrowth into the porous coating provides long-term stability." (Kenna, col. 4, lines 14-17 (emphasis added).) Accordingly, Appellant submits that one skilled in the art would not look to Brantigan for the reasons (e.g., enhanced stability) proposed by the Examiner when Kenna already teaches an implant that provides long-term stability.

(4) The respective rejections of dependent claims 37, 38 and 48, 49 are clearly erroneous.

Dependent claims 37 and 48 each recite "rotating the implant at least one half turn into the opening" and claims 38 and 49 each recite "screwing the implant into the opening."

(a) The proposed combination does not teach or suggest each and every claim element

Appellant disagrees with the Examiner's contention that a "screw or screws spanning the disc space and threadingly engaging adjacent vertebrae, as taught in Crozet . . . would have been an obvious supplement or substitute for the protuberances 5 of Kenna." (Final Action, p. 3, lines 17-20 (emphasis added).) Appellant submits that even if a portion of the implant of Kenna was modified as proposed by the Examiner to include a screw or screws, the implant itself would be inserted into the space linearly and such insertion of the modified Kenna implant would not include "rotating the implant at least one half turn into the opening" as recited in dependent claims 37 and 48 or "screwing the implant into the opening" as recited in dependent claims 38 and 49. Thus, the proposed combination would not result in Appellant's claimed invention. Furthermore, Kenna expressly teaches away from rotating/screwing in the implant by disclosing that positioning tool includes a locking key that "prevents rotation of the implant about the axis of

the positioning tool." (Kenna, col. 5, lines 17-18 (emphasis added).)

(b) There is no rationale to combine Kenna and Crozet because Kenna already achieves, without modification, what the Examiner states is the reason to combine

The Examiner proposes to substitute protuberances 5 of Kenna with the anchorage reinforcement member of Crozet to "improve anchorage and to promote bone fusion." (See Final Action, p. 3, lines 17-21.) Appellant submits that the Examiner's rationale for making the combination falls short of the standard articulated in *KSR* at least because Kenna already teaches that protuberances 5 provide "rotational stability" and "adequate bone ingrowth to stabilize the vertebrae." (See Kenna, col. 4, lines 6-7 and 23.)

(5) The rejection of dependent claim 41 is clearly erroneous because claim 41 recites "providing an implant with a symmetrical trailing end" and the trailing end of the implant of Kenna is asymmetrical. (See Kenna, Fig. 3.) Moreover, the Examiner has provided no reasons to support the rejection of this claim.

III. Conclusion

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Members of the Pre-Appeal Brief Conference reconsider the outstanding rejections in view of the preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-3726.

Respectfully submitted,
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Dated: June 16, 2011

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